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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,349	05/29/2007	Masato Miyake	690121.410USPC	5580

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EXAMINER

EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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12/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,349	Applicant(s) MIYAKE ET AL.	
	Examiner Janet L. Epps-Smith	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 13-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-24-10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-41 are presently pending.
2. Claims 13-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

4. The objection to the drawings set forth in the prior Office Action is withdrawn in response to Applicant's submission of new corrected drawings in compliance with 37 CFR 1.121(d).

Response to Arguments

Claim Rejections - 35 USC § 112

5. The rejection of claims 5-6 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.
6. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Applicants have amended claim 1 to recite wherein the actin acting substance comprises at least amino acids 21 to 241 of SEQ ID NO: 11, constituting an Fn1 domain. However, claim 3 recites wherein the actin acting substance comprises at least

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one protein selected from fibronectin, laminin and vitronectin. It is clear from the specification that the Fn1 domain is part of fibronectin. Therefore, the recitation of laminin and vitronectin in claim 3 does not find support within the scope of claim 1.

8. Claim 4 recites wherein the actin acting substance comprises:

- (a1) a protein molecule having an amino acid sequence set forth in SEQ ID NO.: 2 or 11, or a variant or fragment thereof;
- (b) a polypeptide having an amino acid sequence set forth in SEQ ID NO.: 2 or 11 having at least one mutation selected from the group consisting of at least one amino acid substitution, addition, and deletion, and having a biological activity;
- (c) a polypeptide encoded by a splice or allelic mutant of a base sequence set forth in SEQ IDNO.: 1;
- (d) a polypeptide being a species homolog of the amino acid sequence set forth in SEQ ID NO.: 2 or 11; or
- (e) a polypeptide having an amino acid sequence having at least 70% identity to any one of the polypeptides (a-l) to (d), and having a biological activity.

9. The metes and bounds of claim 4 are vague and indefinite since it is unclear if the composition of claim 4 comprises at least amino acids 21 to 241 of SEQ ID NO: 11, and *further* comprises one of the actin acting substances recited in part (a1) through (e), or if the actin acting substance of claim 1 is to be limited to the one of the actin acting substances recited in part (a1) through (e).

Claim Rejections - 35 USC § 102

10. The rejection of claims 1-4, 7-8, and 11-12 under 35 U.S.C. 102(b) as being anticipated by Hanenberg et al., is withdrawn in response to Applicant's amendment to claim 1.

11. The rejection of claims 1-4 and 7-8 under 35 U.S.C. 102(b) as being anticipated by Rabbani et al. is withdrawn in response to Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

12. Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hanenberg et al. or Rabbani et al. in view of Skorstengaard et al. and Kitazato et al.

13. Applicant's arguments filed 9-21-2010 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that neither Hanenberg et al. nor Rabbani et al. disclose or suggest an actin acting substance comprising at least amino acids 21 to 241 of SEQ ID NO: 11 as claimed. Furthermore, Applicants traversed on the grounds that the deficiencies of these references are not remedied by Skorstengaard et al. Additionally, Applicants appear to suggest that the person of ordinary skill in the art would not have had a reasonable expectation of success to combine the cited references to produce the claimed invention.

14. Contrary to Applicant's assertions, the skilled artisan would have know how to use a polypeptide comprising the Fn1 domain, particularly fibronectin in a manner to increase gene transduction into a cell as evidence by the teachings of Hanenberg et al., which discloses the use of compositions comprising fibronectin to increase the efficiency of retroviral gene transfer. Rabbani et al. also provides guidance to the use of fibronectin as a gene delivery substance. Furthermore, in regards to substituting the fibronectin sequence of Skorstengaard et al. for the fibronectin disclosed in Hanenberg et al. or Rabbani et al., the ordinary skilled artisan would have been motivated to make this modification because as per MPEP § 2144.06 [R-6], it is *prima facie* obvious to substitute art recognized equivalents for the same purpose. Applicant's arguments do not take the place of evidence of nonobviousness.

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15. Secondly it would have been obvious to the ordinary skilled artisan to modify the gene delivery particles described in the primary references with the gold colloid modification of Kitazato et al. since the prior art teaches that this class of modification is well suited for gene delivery vehicles and is useful for visualization of the modified particles.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633